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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,670	04/13/2004	Arthur Earl Colvin JR.	2232-195	2881
6449 7590 11/25/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER GROSS, CHRISTOPHER M				
ART UNIT 1639		PAPER NUMBER		
NOTIFICATION DATE 11/25/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

### Office Action Summary

**Application No.**

10/822,670

**Applicant(s)**

COLVIN ET AL.

**Examiner**

CHRISTOPHER M. GROSS

**Art Unit**

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 7-46 is/are pending in the application.
- 4a) Of the above claim(s) 22-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 36-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.one of ordinary skill in the art****DETAILED ACTION**

Responsive to communications entered 7/17/2007; 8/12/2008. Claims 1-5,7-46 are pending. Claims 22-35 are withdrawn. Claims 1-21, 36-46 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Applicant's election of Polymethylmethacrylate (PMMA) for the species of optically transmissive polymer in the reply filed on 8/12/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Priority***

This application has a filing date of 4/13/2004. Applicant makes no claim for the benefit of any prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

### ***Withdrawn Objection(s) and/or Rejection(s)***

The rejection of claims 8 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention is hereby withdrawn in view of applicant's persuasive arguments.

***Maintained Claim Rejection(s) - 35 USC § 102***

Claims 1-12,14,17-19,36-40 plus 41,44 are rejected under 35 U.S.C. 102(b) as being anticipated by **Singaram et al** (US Patent Application 2002/0106810) and evidenced by Kwok et al (2002 Polymer 45:4017-4027).

Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments: Polymerized hydroxyethylmethacrylate (pHEMA) is a type of optically transmissive polymer, reading on claims 41 and 44.

***Response to Arguments***

In the remarks entered 7/17/2007, applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

In the paragraph bridging pp 14-15, applicant argues Singaram et al do not teach interlacing a macromolecular indicator or monomer thereof with a polymer contained on the *outer surface* of a support which is a sensor or optical waveguide, such as set forth in amended claim 1a.

In this regard, applicant's attention is respectfully invited to figure 4b and paragraphs 0175, where Singaram et al teach a most preferable *semi*-interpenetrating polymer network, which, as shown therein, in contrast to figure 4a of Singaram et al,

does *not* introduce fluorescent dye polymer chains *throughout* the supported quencher polymer (i.e. are relegated to the outer surface).

Please note, in paragraph 0177, Singaram et al teach the reverse topology: supported polymeric dyes interpenetrated with polymerized monomeric quenchers.

From the first full paragraph on p 15 through the first full paragraph on p 16, applicant argues the dye and quencher moieties are both sensing moieties, thus the interpenetrating polymer network according to Singaram et al corresponds to the macromolecular indicator set forth claim 1d for instance of the present invention and as a result, applicant asserts Singaram et al can not be said to teach steps b, d and e of the claimed method.

The examiner respectfully disagrees. By detecting an emission, fluorescent dyes such as the pyrene moieties shown in figure 1 of Singaram et al or more specifically, the polymeric variety discussed above may be used as sensors in of themselves without necessarily the need for quenchers, whereas the opposite is not true (i.e. quenchers can not quench without something to quench). Nevertheless, the term macromolecular indicator set forth claims 1c,d and 36c,d is broad enough to enough to embrace a the polymeric quenchers described in paragraph 0177, discussed above.

Furthermore, regarding steps d and e of claim 1, according to paragraph 0008 of the present specification, "**The polymer chains may be tightened again by the removal of the solvent or by polymerization of the monomer into the hydrophilic macromolecular indicator...**" Emphasis added. In this vein, the examiner respectfully submits, Singaram et al teach tightening by polymerization of the quencher

(macromolecular indicator) in paragraph 0177, reading on claim 36d and concomitantly reading on claims 1d and 1e.

In regard to claim 1b, according to paragraph 0008 of the present specification, **"The polymer chains may be loosened by a solvent such as, for example,** ethanol, 2-methoxyethanol, dimethylformamide, a monomer of a hydrophilic macromolecular indicator such as **HEMA** [hydroxyethylmethacrylate] or mixtures thereof." Emphasis added. In paragraph 0163, Singaram et al teach HEMA as a type of polymer. Thus, in this vein, the examiner respectfully submits, Singaram et al teach loosening by a solvent such as HEMA of the dye polymer in paragraph 0177, reading on claim 1b.

Applicant argues, see paragraph bridging pp 16-17 that Singaram et al does not teach organic solvents to swell polymers but rather the organic solvents are used to dissolve polyhydroxyl analytes. In this regard, as pointed out in the last office action, introduction of ethanol *inherently* swells HEMA polymers as evidenced by Kwok et al cited therein. Nevertheless, the examiner respectfully submits that this point is moot however, given the loosening and tightening mechanism consistent with the present specification discussed above.

***Maintained Claim Rejection(s) - 35 USC § 103***

Claims 1-12,14,17-19, 36-40 plus 41,44 and 13,15-16, 20-21 plus 42,43,45,46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Singaram et al** (US Patent Application 2002/0106810) in view of **Daniloff et al** (US Patent Application

2002/0090734) with evidence provided by Kwok et al (2002 Polymer 45:4017-4027) and Colvin et al (US Patent application 2003/0013204 – IDS entry 4/1/2004)

Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments as follows.

Polymethylmethacrylate (PMMA) represents substituting an art recognized equivalent for the same purpose (an optically transmissive polymer), which forms a basis for obviousness in accordance with MPEP 2144.06(II) and MPEP 2143 rationale B as codified in KSR International Co. v. Teleflex Inc., 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1395-97 (2007).

Here, evidence provided in paragraph 0028 of Kelman (US Patent Application 2004/0006387) indicates the PMMA (elected species) set forth in claims 42-43 and 45-46 is an art recognized optically transmissive polymer substitutable for the pHEMA according to Singaram et al, as

#### *Response to Arguments*

Applicant argues, see remarks entered 7/17/2007: (i) not all elements are taught; (ii) a lack of motivation; (iii) no expectation of success.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

(i) In the paragraph bridging pp 17-18, applicant argues Singaram et al do not teach: (1) providing a support having an outer surface which comprises at least one polymer wherein the support is either a sensor or optical waveguide; (2) changing the

integrity of (swelling) said polymer to provide loosened polymer chains that for at least one interlacing area on the outer surface of the support; (3) causing a macromolecular indicator to interlace with said at least one interlacing area on the outer surface of said support; (4) causing the loosened polymer chains to tighten to produce surface immobilized indicator molecules; (5) Singaram et al is silent as to the need of interlacing the polymer of the outer surface of the support and the macromolecular indicator so that a primary function or characteristic of the support is substantially preserved after immobilization. Accordingly, applicant asserts one of skill in the art would not have been motivated to "come up" with the claimed method nor had a reasonable expectation of success in interlacing the macromolecular indicator directly with the polymer "directly" with the polymer on the outer surface of the support.

(1-4) Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 102 rejection, above. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above sections, which are incorporated in their entireties herein by reference.

(5) With regard to Singaram et al being silent as to the need of interlacing the polymer of the outer surface of the support and the macromolecular indicator so that a primary function or characteristic of the support is substantially preserved after immobilization, applicants attention is respectfully invited to paragraph 0177 where, Singaram et al state "In either case, the molecular weight of the soluble component must be sufficiently high (about or greater than 10,000 daltons) that it cannot diffuse out



of the network, i.e. **it becomes physically bound to or trapped by the matrix**" and paragraph 0055 which states "Optionally, **the components are separated** from the analyte solution **by a membrane which is impermeable to the sensing components**, but permeable to the analyte." Emphasis added. Here, the examiner respectfully submits that Singaram et al is well aware of the need to retain the fluorescent dye and quencher elements either within the confines of the matrix by use of an interpenetrating network or else a employ a semi-permeable membrane to preserve the primary function, that of as a sensing apparatus.

Therefore, the examiner most respectfully submits one of skill in the art would not need to "come up" with the claimed method, as it is explicitly taught by Singaram et al. And further one of skill in the art would have had a reasonable expectation of success in interlacing the macromolecular indicator (quencher) directly with the polymer with the fluorescent dye sensor polymer on the outer surface of the support by using a semi-interpenetrating polymer network, advocated by Singaram et al.

***New Claim Rejection(s) – 35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns "new matter."

*This rejection is necessitated by Applicant's amendment to the claims.*

Claims 1 and 36 have been amended to add limitations concerning *outer* surfaces.

The specification as originally filed provided no implicit or explicit support for interlacing outer surfaces.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often

necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHRISTOPHER M. GROSS** whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

cg

/Christopher S. F. Low/  
Supervisory Patent Examiner, Art Unit 1639

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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18 Nov 2008